EN
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Answer given by Ms Kyriakides
on behalf of the European Commission
(1.5.2021)

The Commission has granted conditional marketing authorisations (CMAs) for the COVID-19 vaccines developed by BioNTech/Pfizer (Comirnaty)[1], Moderna[2], AstraZeneca[3] and Janssen Pharmaceutica[4]. Each CMA followed a scientific opinion of the European Medicines Agency (EMA) on a positive benefit-risk balance for the use of the specific vaccine - based on evaluation of its quality, safety and efficacy.

The EU legislation foresees CMAs specifically for public health emergencies. CMAs are valid for one year and can be renewed annually. Different specific obligations (SOs) are imposed on each of the COVID-19 vaccines, depending on the particular data/studies required by the EMA for that vaccine. The SOs are publicly available. For instance, the assessment report[5] of Comirnaty detail the SOs imposed on this vaccine, with a summary table including deadlines. Documents published in all languages explain the information awaited for Comirnaty[6][7].

Information on possible known side effects of a vaccine is published in the product information. Marketing authorisation holders are obliged to record and inform of any new case report about adverse events to ensure a tight safety monitoring in line with the pharmacovigilance provisions of the EU legislation.

The definition of health policy, as well as the organisation and delivery of health services and medical care, including their management and allocation of resources assigned to them, is a Member State competence under Article 168 of the Treaty of the Functioning of the EU[8]. Compensation procedures for medicines side effects are also decided at national level.

[1] https://ec.europa.eu/health/documents/community-register/html/h1528.htm
[2] https://ec.europa.eu/health/documents/community-register/html/h1507.htm
[3] https://ec.europa.eu/health/documents/community-register/html/h1529.htm
[4] https://ec.europa.eu/health/documents/community-register/html/h1525.htm
[5] https://www.ema.europa.eu/en/documents/assessment-report/comirnaty-epar-public-assessment-report_en.pdf
[6] https://www.ema.europa.eu/en/medicines/human/EPAR/comirnaty
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[8] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12008E168&from=EN